IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC, Plaintiff, v. AMNEAL PHARMACEUTICALS GMBH, AMNEAL PHARMACEUTICALS OF NEW YORK LLC, AMNEAL BIOSCIENCES LLC, AMNEAL PHARMACEUTICAL HOLDING COMPANY LLC, and AMNEAL PHARMACEUTICAL PVT. LTD, Defendants.	C.A. No. 19-712-CFC

AMNEAL PHARMACEUTICALS GMBH, AMNEAL PHARMACEUTICALS OF NEW YORK LLC, AMNEAL BIOSCIENCES LLC, AND AMNEAL PHARMACEUTICAL PVT. LTD'S ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendants Amneal Pharmaceuticals GMBH, Amneal Pharmaceuticals of New York LLC, Amneal Biosciences LLC, and Amneal Pharmaceutical PVT. LTD (collectively, "Amneal") hereby answer the Complaint filed by Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively, "Par" or "Plaintiffs") by denying each and every allegation contained therein, except those that are specifically admitted, modified, or qualified in this Answer. Amneal bases its responses on its knowledge as to its own activities, and on information and belief as to the activities of others. The numbered paragraphs below correspond to the numbered paragraphs in the Complaint.

THE PARTIES

1. Amneal lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 and therefore denies the same.

2. Amneal lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 and therefore denies the same.

3. Amneal lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 and therefore denies the same.

4. Amneal admits that Amneal Pharmaceuticals Company GmbH ("Amneal GmbH") is a limited liability company organized and existing under the laws of Switzerland, having its principal place of business at Turmstrasse 30 6312, Steinhausen, Switzerland. Amneal admits that Amneal GmbH develops, manufactures, markets, and distributes pharmaceutical products for sale in the State of Delaware and throughout the United States. Otherwise denied.

5. Amneal admits that Amneal Pharmaceuticals of New York ("Amneal New York") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 50 Horseblock Road, Brookhaven, New York 11719. Amneal admits that Amneal New York develops, produces, and distributes pharmaceutical products for sale in the State of Delaware and throughout the United States. Otherwise denied.

6. Amneal admits that Amneal Biosciences LLC ("Amneal Biosciences") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 400 Crossing Boulevard, Floor 3, Bridgewater, New Jersey 08807. Amneal admits that Amneal Biosciences distributes pharmaceutical products for sale in the State of Delaware and throughout the United States. Otherwise denied.

7. Amneal admits that Amneal Pharmaceuticals Holding Company, LLC ("Amneal Holding") is a limited liability company organized and existing under the laws of Delaware, having a place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. Otherwise denied.

8. Amneal admits that Amneal Pharmaceuticals Pvt. Ltd. ("Amneal India") is a limited liability company organized and existing under the laws of India, having a place of business at Plot No. 15, PHARMEZ Special Economic Zone, Sarkhej-Bavia N.H., No. 8A, Vil.: Matoda, Tal.:Sanand, Ahmedabad, Gujarat 382213, India. Amneal admits that Amneal India manufactures, packages, tests, and ships pharmaceutical products to the United States. Otherwise denied.

NATURE OF THE ACTION

9. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Amneal admits that the Complaint purports to state claims arising under the patent laws of the United States, Title 35 §§ 101 *et seq*., and alleges infringement of United States Patent Nos. 9,744,209 and 9,750,785. Otherwise denied.

JURISDICTION AND VENUE

10. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, for the purposes of this case only, Amneal does not contest subject matter jurisdiction. Otherwise denied.

11. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, for the purposes of this case only, Amneal New York does not contest personal jurisdiction. Otherwise denied.

12. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, for the purposes of this case only, Amneal GmbH does not contest personal jurisdiction. Otherwise denied.

13. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, for the purposes of this case only, Amneal Biosciences does not contest personal jurisdiction. Otherwise denied.

14. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, paragraph 14 is directed to a separate party and therefore Amneal denies the same. Otherwise denied.

15. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, for the purposes of this case only, Amneal India does not contest personal jurisdiction. Otherwise denied.

16. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, for the purposes of this case only, Amneal does not contest venue in this district. Otherwise denied.

THE DRUG APPROVAL PROCESS

17. This paragraph states a legal conclusion to which no response is required. Amneal admits that FDA approval is required to market a new pharmaceutical drug in the United States and the FDA maintains the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." Otherwise denied.

18. This paragraph states a legal conclusion to which no response is required. Amneal admits that a company seeking to market a generic version of a drug may submit to the FDA an Abbreviated New Drug Application ("ANDA") showing the generic version to be bioequivalent to a previously approved drug. Otherwise denied.

19. This paragraph states a legal conclusion to which no response is required. Amneal admits that Congress has enacted a statutory scheme that allows parties to resolve patent disputes related to generic drugs and that the statute requires ANDA filers to file certifications with respect to each patent listed in the Orange Book. Otherwise denied.

20. This paragraph states a legal conclusion to which no response is required. Amneal admits that an ANDA filer must provide notice to the patent owner and NDA holder of

any Paragraph IV Certifications, and the notice must include a detailed statement of the factual and legal bases for applicant's belief that the challenged patents are invalid or not infringed by the proposed generic product. Otherwise denied.

21. This paragraph states a legal conclusion to which no response is required. Amneal admits that the statute provides for a 30-month stay of FDA approval in certain circumstances. Otherwise denied.

FACTUAL BACKGROUND

The Patents-In-Suit

22. Amneal admits that according to the face of United States Patent No. 9,744,209 ("the '209 patent"), the '209 patent issued on August 29, 2017, and is titled "Vasopressin Formulations For Use in Treatment of Hypotension." Amneal further admits that what purports to be a copy of the '209 patent is attached to the Complaint as Exhibit A. The remaining allegations in paragraph 22 state a legal conclusion to which no response is required. To the extent a response is required, Amneal lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 22 and therefore denies the same.

23. Amneal admits that according to the face of United States Patent No. 9,750,785 ("the '785 patent"), the '785 patent issued on September 5, 2017, and is titled "Vasopressin Formulations For Use in Treatment of Hypotension." Amneal further admits that what purports to be a copy of the '785 patent is attached to the Complaint as Exhibit B. The remaining allegations in paragraph 23 state a legal conclusion to which no response is required. To the extent a response is required, Amneal lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23 and therefore denies the same.

24. Amneal lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 24 and therefore denies the same.

VASOSTRICT®

25. Amneal admits that Vasopressin is the active ingredient in VASOSTRICT®. Amneal further admits VASOSTRICT® is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hyposensitive despite fluids and catecholamines. Otherwise denied.

26. Upon information and belief Amneal admits that on April 17, 2014, the FDA approved NDA 204485. Otherwise Amneal lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 26 and therefore denies the same.

27. Amneal lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 27 and therefore denies the same.

28. Upon information and belief admitted.

29. Upon information and belief admitted.

30. Amneal lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 30 and therefore denies the same

31. Amneal admits that VASOSTRICT® is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. Amneal lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 31 and therefore denies the same.

Amneal's Generic Vasopressin Injection Product

32. Amneal admits that it submitted ANDA No. 212944 to the FDA pursuant to 35 U.S.C. §355(j), seeking approval to market Vasopressin Injection USP, 20 units/1mL (20 units/mL) product. Otherwise denied.

33. Amneal admits that Amneal sent Plaintiffs a notice stating that Amneal had submitted ANDA No. 212944. The notice speaks for itself and is the best source for its content.

Otherwise denied.

34. Amneal admits that Amneal sent Plaintiffs a Paragraph IV Notice regarding Amneal's ANDA No. 212944. The notice speaks for itself and is the best source for its content. Otherwise denied.

35. Amneal admits that it submitted ANDA No. 212945 to the FDA pursuant to 35 U.S.C. §355(j), seeking approval to market Vasopressin Injection USP, 200 units/10mL (20 units/mL) product. Otherwise denied.

36. Amneal admits that Amneal sent Plaintiffs a notice stating that Amneal had submitted ANDA No. 212945. The notice speaks for itself and is the best source for its content. Otherwise denied.

37. Amneal admits that Amneal sent Plaintiffs a Paragraph IV Notice regarding Amneal's ANDA No. 212945. The notice speaks for itself and is the best source for its content. Otherwise denied.

38. Amneal is without knowledge or information sufficient to form a belief as to the allegations in paragraph 38 and therefore denies the same.

39. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

COUNT I:
INFRINGEMENT OF THE '785 PATENT (AMNEAL ANDA NO. 212944)

40. Amneal incorporates its responses to paragraphs 1-39 as if fully set forth herein.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

46. Amneal admits that it is aware of the existence of the '785 patent. Otherwise denied.

47. Denied.

COUNT II:
INFRINGEMENT OF THE '209 PATENT (AMNEAL ANDA NO. 212944)

48. Amneal incorporates its responses to paragraphs 1-47 as if fully set forth herein.

49. Denied.

50. Denied.

51. Denied.

52. Denied.

53. Denied.

54. Amneal admits that it is aware of the existence of the '209 patent. Otherwise denied.

55. Denied.

COUNT III:
INFRINGEMENT OF THE '785 PATENT (AMNEAL ANDA NO. 212945)

56. Amneal incorporates its responses to paragraphs 1-55 as if fully set forth herein.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Amneal admits that it is aware of the existence of the '785 patent. Otherwise denied.

63. Denied.

COUNT IV:

INFRINGEMENT OF THE '209 PATENT (AMNEAL ANDA NO. 212945)

64. Amneal incorporates its responses to paragraphs 1-63 as if fully set forth herein.

65. Denied.

66. Denied.

67. Denied.

68. Denied.

69. Denied.

70. Amneal admits that it is aware of the existence of the '209 patent. Otherwise denied.

71. Denied.

PLAINTIFFS' PRAYER FOR RELIEF

Amneal denies that Plaintiffs are entitled to any of the relief sought in their prayer for relief or any relief whatsoever.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in this Answer, Amneal further responds to the Complaint with the defenses set forth below. Amneal expressly reserves the right to supplement this Answer, including the right to assert additional defenses as more information is learned through discovery and further factual investigation in this case. Amneal does not intend to hereby assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof.

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

The Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE
(Non-infringement of the '785 patent)

The manufacture, use, offer for sale, sale, or importation of the Amneal ANDA Product, that is the subject of ANDA No. 212944, has not, does not, and will not infringe any valid and enforceable claim of the '785 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents or in any manner.

The manufacture, use, offer for sale, sale, or importation of the Amneal ANDA Product, that is the subject of ANDA No. 212945, has not, does not, and will not infringe any valid and enforceable claim of the '785 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents or in any manner.

THIRD AFFIRMATIVE DEFENSE
(Invalidity of the '785 patent)

Each of the claims of the '785 patent are invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112, or 116, and the rules, regulations and laws for pertaining thereto, and/or for obviousness-type double patenting.

FOURTH AFFIRMATIVE DEFENSE
(Non-infringement of the '209 patent)

The manufacture, use, offer for sale, sale, or importation of the Amneal ANDA Product, that is the subject of ANDA No. 212944, has not, does not, and will not infringe any valid and enforceable claim of the '209 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents or in any manner.

The manufacture, use, offer for sale, sale, or importation of the Amneal ANDA Product, that is the subject of ANDA No. 212945, has not, does not, and will not infringe any valid and

enforceable claim of the '209 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents or in any manner.

FIFTH AFFIRMATIVE DEFENSE
(Invalidity of the '209 patent)

Each of the claims of the '209 patent are invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112, or 116, and the rules, regulations and laws for pertaining thereto, and/or for obviousness-type double patenting.

SIXTH AFFIRMATIVE DEFENSE
(No Costs)

Plaintiffs are barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

SEVENTH AFFIRMATIVE DEFENSE
(No Injunctive Relief)

Plaintiffs may not seek injunctive relief against Amneal because Plaintiffs' alleged damages are not immediate or irreparable, and Plaintiffs therefore have an adequate remedy at law.

EIGHTH AFFIRMATIVE DEFENSE
(Reservation of Rights)

Amneal specifically reserves the right to assert each and every other defense that may become evident in the course of discovery.

WHEREFORE, Amneal prays that this Court enter an order:

A. Dismissing the Complaint, with prejudice, and denying Plaintiffs the relief requested in the Complaint and any relief whatsoever;

B. Denying Plaintiffs any award of damages, costs, or fees;

C. Declaring this case exceptional and awarding Amneal reasonable attorneys' fees;

D. Awarding Amneal its costs; and

E. Granting such other and further relief as this Court may deem just.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Without admitting any of the allegations of Plaintiffs other than those expressly admitted herein, and without prejudice to the rights of Amneal to plead additional Counterclaims as the facts of the matter warrant, Defendants and Counterclaim-Plaintiffs, Amneal, hereby submit these Counterclaims against Plaintiffs and Counterclaim-Defendants:

PARTIES

1. Counterclaim Plaintiff Amneal Pharmaceuticals Company GmbH ("Amneal GmbH") is a limited liability company organized and existing under the laws of Switzerland, having its principal place of business at Turmstrasse 30 6312, Steinhausen, Switzerland.

2. Counterclaim Plaintiff Amneal Pharmaceuticals of New York ("Amneal New York") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 50 Horseblock Road, Brookhaven, New York 11719.

3. Counterclaim Plaintiff Amneal Biosciences LLC ("Amneal Biosciences") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 400 Crossing Boulevard, Floor 3, Bridgewater, New Jersey 08807.

4. Counterclaim Defendant Par Pharmaceutical, Inc. ("Par Pharmaceutical") has averred that it is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

5. Counterclaim Defendant Par Sterile Products, LLC ("Par Sterile Products") has averred that it is a limited liability company organized and existing under the laws of Delaware, having its principal places of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

6. Counterclaim Defendant Endo Par Innovation Company ("EPIC") has averred

that it is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

JURISDICTION AND VENUE

7. This is a declaratory judgment action arising under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. Personal jurisdiction over Counterclaim Defendants Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively, "Counterclaim Defendants" or "Par") is proper because, *inter alia*, Counterclaim Defendants subjected themselves to the Court's personal jurisdiction by filing the Complaint in the above action in this Court, and because, on information and belief, either directly or through agents, they transact business in, and derive substantial revenue from, Delaware.

9. Venue is proper in this District under 28 U.S.C. §§ 1391, and as a result of Plaintiffs' choice of forum.

BACKGROUND

10. United States Patent No. 9,744,209 ("the '209 patent") is titled "Vasopressin Formulations for Use in Treatment of Hypotension" and states that it was issued on August 29, 2017.

11. United States Patent No. 9,750,785 ("the '785 patent") is titled "Vasopressin Formulations for Use in Treatment of Hypotension" and states that it was issued on September 5, 2017.

12. United States Patent No. 9,375,478 ("the '478 patent") is titled "Vasopressin

Formulations for Use in Treatment of Hypotension" and states that it was issued on June 28, 2016. A true and correct copy of the '478 patent is attached as Exhibit 1.

13. United States Patent No. 9,687,526 ("the '526 patent") is titled "Vasopressin Formulations for Use in Treatment of Hypotension" and states that it was issued on June 27, 2017. A true and correct copy of the '526 patent is attached as Exhibit 2.

14. United States Patent No. 9,744,239 ("the '239 patent") is titled "Vasopressin Formulations for Use in Treatment of Hypotension" and states that it was issued on August 29, 2017. A true and correct copy of the '239 patent is attached as Exhibit 3.

15. The '209, '785, '478, '526, and '239 patents are listed in Approved Drug Products with Therapeutic Evaluations ("the Orange Book") for New Drug Application ("NDA") Nos. 204485/S-003 and 204485/S-004 for Vasopressin Injection USP, 20 units/mL in 1 mL vials and 200 units/10mL in 10 mL multi-dose vials, respectively, which are marketed in the United States under the trade name VASOSTRICT®.

16. Counterclaim Defendant Par Pharmaceutical, Inc. has averred that it is the owner of the '785 and '209 patents by virtue of assignment.

17. On information and believe Defendant Par Pharmaceutical, Inc. is the owner of the '478, '526, and '239 patents by virtue of assignment.

18. On April 18, 2019, Counterclaim Defendants filed this lawsuit alleging infringement of the '785 and '209 patents.

19. Amneal submitted ANDA No. 212944 (the "Amneal Single-Dose ANDA") to the FDA pursuant to 21 U.S.C. § 355(j) seeking approval for the commercial manufacture, use, or sale in the United States of Vasopressin Injection USP, 20 units/1 mL (20 units/mL) product. The Amneal Single-Dose ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV)

of the Federal, Food, Drug and Cosmetic Act ("FDCA") that the '209, '785, '478, '526, and '239 patents are invalid and/or will not be infringed by the Amneal Single-Dose ANDA Product.

20. Amneal sent notice of that certification to Counterclaim Defendants on or about March 5, 2019. Upon information and belief, and as Counterclaim Defendants allege in their Complaint, Counterclaim Defendants received that notification.

21. Amneal submitted ANDA No. 212945 (the "Amneal Multi-Dose ANDA") to the FDA pursuant to 21 U.S.C. § 355(j) seeking approval for the commercial manufacture, use, or sale in the United States of Vasopressin Injection USP, 200 units/10 mL (20 units/mL) product. The Amneal Multi-Dose ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal, Food, Drug and Cosmetic Act ("FDCA") that the '209, '785, '478, '526, and '239 patents are invalid and/or will not be infringed by the Amneal Multi-Dose ANDA Product.

22. Amneal sent notice of that certification to Counterclaim Defendants on or about March 5, 2019. Upon information and belief, and as Counterclaim Defendants allege in their Complaint, Counterclaim Defendants received that notification.

23. As a consequence of the foregoing, there is an actual and justiciable controversy as to the infringement and validity of the '785,'209, '478, '526, and '239 patents. This controversy is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

COUNTERCLAIM I
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '785 PATENT (AMNEAL'S ANDA NO. 212944)

24. Amneal adopts by reference, repeats, and realleges its specific allegations and averments in the preceding paragraphs as if fully set forth herein.

25. Amneal has not infringed any asserted claim of the '785 patent, either literally or under the doctrine of equivalents, and the commercial manufacture, use, offer for sale, sale or

importation of the Amneal Single-Dose ANDA Product by Amneal would not directly infringe any claim of the '785 patent, either literally or under the doctrine of equivalents because Amneal's Single-Dose ANDA Product does not meet all the limitations of any claim of the '785 patent.

26. Amneal is entitled to a judgment declaring that Amneal has not infringed any asserted claim of the '785 patent, either literally or under the doctrine of equivalents, and that the commercial manufacture, use, offer for sale, sale or importation of the Amneal Single-Dose ANDA Product by Amneal would not directly infringe any claim of the '785 patent, either literally or under the doctrine of equivalents.

27. Amneal is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Plaintiffs in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

COUNTERCLAIM II

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '785 PATENT (AMNEAL'S ANDA NO. 212945)

28. Amneal adopts by reference, repeats, and realleges its specific allegations and averments in the preceding paragraphs as if fully set forth herein.

29. Amneal has not infringed any asserted claim of the '785 patent, either literally or under the doctrine of equivalents, and the commercial manufacture, use, offer for sale, sale or importation of the Amneal Multi-Dose ANDA Product by Amneal would not directly infringe any claim of the '785 patent, either literally or under the doctrine of equivalents because Amneal's Multi-Dose ANDA Product does not meet all the limitations of any claim of the '785 patent.

30. Amneal is entitled to a judgment declaring that Amneal has not infringed any

asserted claim of the '785 patent, either literally or under the doctrine of equivalents, and that the commercial manufacture, use, offer for sale, sale or importation of the Amneal Multi-Dose ANDA Product by Amneal would not directly infringe any claim of the '785 patent, either literally or under the doctrine of equivalents.

31. Amneal is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Plaintiffs in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

COUNTERCLAIM III
DECLARATORY JUDGMENT OF INVALIDITY OF THE '785 PATENT

32. Amneal adopts by reference, repeats, and realleges its specific allegations and averments in the preceding paragraphs as if fully set forth herein.

33. Each of the claims of the '785 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112 or 116, and the rules, regulations, and laws pertaining thereto, and/or for obviousness-type double patenting. For example, each claim of the '785 patent is invalid under 35 U.S.C. § 112 because it does not adequately describe the claim limitation wherein "the unit dosage form further comprises impurities that are present in an amount of 0.9% - 1.7%, wherein the impurities have from about 85% to about 100% sequence homology" to vasopressin.

34. Amneal is entitled to a judicial declaration that each of the claims of the '785 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112 or 116, and the rules, regulations, and laws pertaining thereto, and/or for obviousness-type double patenting.

35. Amneal is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Counterclaim Defendants in accordance with the provisions

of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

COUNTERCLAIM IV
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '209 PATENT
(AMNEAL'S ANDA NO. 212944)

36. Amneal adopts by reference, repeats, and realleges its specific allegations and averments in the preceding paragraphs as if fully set forth herein.

37. Amneal has not infringed any asserted claim of the '209 patent, either literally or under the doctrine of equivalents, and the commercial manufacture, use, offer for sale, sale or importation of the Amneal Single-Dose ANDA Product by Amneal would not directly infringe any claim of the '209 patent, either literally or under the doctrine of equivalents because Amneal's Single-Dose ANDA Product does not meet all the limitations of any claim of the '209 patent.

38. Amneal is entitled to a judgment declaring that Amneal has not infringed any asserted claim of the '209 patent, either literally or under the doctrine of equivalents, and that the commercial manufacture, use, offer for sale, sale or importation of the Amneal Single-Dose ANDA Product by Amneal would not directly infringe any claim of the '209 patent, either literally or under the doctrine of equivalents.

39. Amneal is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Plaintiffs in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

COUNTERCLAIM V
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '209 PATENT
(AMNEAL'S ANDA NO. 212945)

40. Amneal adopts by reference, repeats, and realleges its specific allegations and averments in the paragraphs 1-32 as if fully set forth herein.

41. Amneal has not infringed any asserted claim of the '209 patent, either literally or

under the doctrine of equivalents, and the commercial manufacture, use, offer for sale, sale or importation of the Amneal Multi-Dose ANDA Product by Amneal would not directly infringe any claim of the '209 patent, either literally or under the doctrine of equivalents because Amneal's Multi-Dose ANDA Product does not meet all the limitations of any claim of the '209 patent.

42. Amneal is entitled to a judgment declaring that Amneal has not infringed any asserted claim of the '209 patent, either literally or under the doctrine of equivalents, and that the commercial manufacture, use, offer for sale, sale or importation of the Amneal Multi-Dose ANDA Product by Amneal would not directly infringe any claim of the '209 patent, either literally or under the doctrine of equivalents.

43. Amneal is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Plaintiffs in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

COUNTERCLAIM VI
DECLARATORY JUDGMENT OF INVALIDITY OF THE '209 PATENT

44. Amneal adopts by reference, repeats, and realleges its specific allegations and averments in the preceding paragraphs as if fully set forth herein.

45. Each of the claims of the '209 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112 or 116, and the rules, regulations, and laws pertaining thereto, and/or for obviousness-type double patenting. For example, the '209 patent is invalid under 35 U.S.C. § 112 because it does not adequately describe the claim limitation wherein "the unit dosage form further comprises impurities that are present in an amount of 0.9% - 1.7%, wherein the impurities have from about 85% to about 100% sequence homology" to vasopressin.

46. Amneal is entitled to a judicial declaration that each of the claims of the '209 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112 or 116, and the rules, regulations, and laws pertaining thereto, and/or for obviousness-type double patenting.

47. Amneal is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

COUNTERCLAIM VII
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '478 PATENT (AMNEAL'S ANDA NO. 212944)

48. Amneal adopts by reference, repeats, and realleges its specific allegations and averments in the preceding paragraphs as if fully set forth herein.

49. Amneal has not infringed any asserted claim of the '478 patent, either literally or under the doctrine of equivalents, and the commercial manufacture, use, offer for sale, sale or importation of the Amneal Single-Dose ANDA Product by Amneal would not directly infringe any claim of the '478 patent, either literally or under the doctrine of equivalents because Amneal's Single-Dose ANDA Product does not meet all the limitations of any claim of the '478 patent.

50. Amneal is entitled to a judgment declaring that Amneal has not infringed any asserted claim of the '478 patent, either literally or under the doctrine of equivalents, and that the commercial manufacture, use, offer for sale, sale or importation of the Amneal Single-Dose ANDA Product by Amneal would not directly infringe any claim of the '478 patent, either literally or under the doctrine of equivalents.

51. Amneal is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Plaintiffs in accordance with the provisions of 35 U.S.C. §

285 or such other authorities as the Court deems applicable.

COUNTERCLAIM VIII
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '478 PATENT (AMNEAL'S ANDA NO. 212945)

52. Amneal adopts by reference, repeats, and realleges its specific allegations and averments in the paragraphs 1-32 as if fully set forth herein.

53. Amneal has not infringed any asserted claim of the '478 patent, either literally or under the doctrine of equivalents, and the commercial manufacture, use, offer for sale, sale or importation of the Amneal Multi-Dose ANDA Product by Amneal would not directly infringe any claim of the '478 patent, either literally or under the doctrine of equivalents because Amneal's Multi-Dose ANDA Product does not meet all the limitations of any claim of the '478 patent.

54. Amneal is entitled to a judgment declaring that Amneal has not infringed any asserted claim of the '478 patent, either literally or under the doctrine of equivalents, and that the commercial manufacture, use, offer for sale, sale or importation of the Amneal Multi-Dose ANDA Product by Amneal would not directly infringe any claim of the '478 patent, either literally or under the doctrine of equivalents.

55. Amneal is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Plaintiffs in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

COUNTERCLAIM IX
DECLARATORY JUDGMENT OF INVALIDITY OF THE '478 PATENT

56. Amneal adopts by reference, repeats, and realleges its specific allegations and averments in the preceding paragraphs as if fully set forth herein.

57. Each of the claims of the '478 patent is invalid for failure to comply with one or

more requirements of 35 U.S.C. §§ 101, 102, 103, 112 or 116, and the rules, regulations, and laws pertaining thereto, and/or for obviousness-type double patenting.

58. Amneal is entitled to a judicial declaration that each of the claims of the '478 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112 or 116, and the rules, regulations, and laws pertaining thereto, and/or for obviousness-type double patenting.

59. Amneal is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

COUNTERCLAIM X
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '526 PATENT (AMNEAL'S ANDA NO. 212944)

60. Amneal adopts by reference, repeats, and realleges its specific allegations and averments in the preceding paragraphs as if fully set forth herein.

61. Amneal has not infringed any asserted claim of the '526 patent, either literally or under the doctrine of equivalents, and the commercial manufacture, use, offer for sale, sale or importation of the Amneal Single-Dose ANDA Product by Amneal would not directly infringe any claim of the '526 patent, either literally or under the doctrine of equivalents because Amneal's Single-Dose ANDA Product does not meet all the limitations of any claim of the '526 patent.

62. Amneal is entitled to a judgment declaring that Amneal has not infringed any asserted claim of the '526 patent, either literally or under the doctrine of equivalents, and that the commercial manufacture, use, offer for sale, sale or importation of the Amneal Single-Dose ANDA Product by Amneal would not directly infringe any claim of the '526 patent, either literally or under the doctrine of equivalents.

63. Amneal is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Plaintiffs in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

COUNTERCLAIM XI
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '526 PATENT (AMNEAL'S ANDA NO. 212945)

64. Amneal adopts by reference, repeats, and realleges its specific allegations and averments in the paragraphs 1-32 as if fully set forth herein.

65. Amneal has not infringed any asserted claim of the '526 patent, either literally or under the doctrine of equivalents, and the commercial manufacture, use, offer for sale, sale or importation of the Amneal Multi-Dose ANDA Product by Amneal would not directly infringe any claim of the '526 patent, either literally or under the doctrine of equivalents because Amneal's Multi-Dose ANDA Product does not meet all the limitations of any claim of the '526 patent..

66. Amneal is entitled to a judgment declaring that Amneal has not infringed any asserted claim of the '526 patent, either literally or under the doctrine of equivalents, and that the commercial manufacture, use, offer for sale, sale or importation of the Amneal Multi-Dose ANDA Product by Amneal would not directly infringe any claim of the '526 patent, either literally or under the doctrine of equivalents.

67. Amneal is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Plaintiffs in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

COUNTERCLAIM XII
DECLARATORY JUDGMENT OF INVALIDITY OF THE '526 PATENT

68. Amneal adopts by reference, repeats, and realleges its specific allegations and

averments in the preceding paragraphs as if fully set forth herein.

69. Each of the claims of the ’526 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112 or 116, and the rules, regulations, and laws pertaining thereto, and/or for obviousness-type double patenting.

70. Amneal is entitled to a judicial declaration that each of the claims of the ’526 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112 or 116, and the rules, regulations, and laws pertaining thereto, and/or for obviousness-type double patenting.

71. Amneal is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

COUNTERCLAIM XIII
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’239 PATENT (AMNEAL’S ANDA NO. 212944)

72. Amneal adopts by reference, repeats, and realleges its specific allegations and averments in the preceding paragraphs as if fully set forth herein.

73. Amneal has not infringed any asserted claim of the ’239 patent, either literally or under the doctrine of equivalents, and the commercial manufacture, use, offer for sale, sale or importation of the Amneal Single-Dose ANDA Product by Amneal would not directly infringe any claim of the ’239 patent, either literally or under the doctrine of equivalents because Amneal’s Single-Dose ANDA Product does not meet all the limitations of any claim of the ’239 patent..

74. Amneal is entitled to a judgment declaring that Amneal has not infringed any asserted claim of the ’239 patent, either literally or under the doctrine of equivalents, and that the commercial manufacture, use, offer for sale, sale or importation of the Amneal Single-Dose

ANDA Product by Amneal would not directly infringe any claim of the '239 patent, either literally or under the doctrine of equivalents.

75. Amneal is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Plaintiffs in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

COUNTERCLAIM XIV
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '239 PATENT (AMNEAL'S ANDA NO. 212945)

76. Amneal adopts by reference, repeats, and realleges its specific allegations and averments in the paragraphs 1-32 as if fully set forth herein.

77. Amneal has not infringed any asserted claim of the '239 patent, either literally or under the doctrine of equivalents, and the commercial manufacture, use, offer for sale, sale or importation of the Amneal Multi-Dose ANDA Product by Amneal would not directly infringe any claim of the '239 patent, either literally or under the doctrine of equivalents because Amneal's Multi-Dose ANDA Product does not meet all the limitations of any claim of the '239 patent.

78. Amneal is entitled to a judgment declaring that Amneal has not infringed any asserted claim of the '239 patent, either literally or under the doctrine of equivalents, and that the commercial manufacture, use, offer for sale, sale or importation of the Amneal Multi-Dose ANDA Product by Amneal would not directly infringe any claim of the '239 patent, either literally or under the doctrine of equivalents.

79. Amneal is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Plaintiffs in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

COUNTERCLAIM XV
DECLARATORY JUDGMENT OF INVALIDITY OF THE '239 PATENT

80. Amneal adopts by reference, repeats, and realleges its specific allegations and averments in the preceding paragraphs as if fully set forth herein.

81. Each of the claims of the '239 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112 or 116, and the rules, regulations, and laws pertaining thereto, and/or for obviousness-type double patenting.

82. Amneal is entitled to a judicial declaration that each of the claims of the '239 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112 or 116, and the rules, regulations, and laws pertaining thereto, and/or for obviousness-type double patenting.

83. Amneal is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

PRAYER FOR RELIEF

WHEREFORE, Amneal respectfully requests that this Court grant the following relief against Counterclaim Defendants:

A. Dismissing with prejudice the entirety of Counterclaim Defendants' Complaint;

B. Denying all remedies and relief sought by Counterclaim Defendants in the Complaint;

C. Declaring that Amneal has not infringed, and is not infringing, literally or under the doctrine of equivalents, any valid claim of the '785 patent;

D. Declaring that each and every asserted claim of the '785 patent is invalid;

E. Declaring that Amneal has not infringed, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '209 patent;

F. Declaring that each and every asserted claim of the '209 patent is invalid;

G. Declaring that Amneal has not infringed, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '478 patent;

H. Declaring that each and every asserted claim of the '478 patent is invalid

I. Declaring that Amneal has not infringed, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '526 patent;

J. Declaring that each and every asserted claim of the '526 patent is invalid

K. Declaring that Amneal has not infringed, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '239 patent;

L. Declaring that each and every asserted claim of the '239 patent is invalid

M. Finding this to be an exceptional case and awarding Amneal reasonable attorney fees and costs under 35 U.S.C. § 285; and all other applicable statutes and rules in common law that would be appropriate, with pre- and post-judgment interest thereon; and

N. Granting such other and further relief as this Court may deem just and proper.

Dated: June 12, 2019

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CERTIFICATE OF SERVICE

I, Anne Shea Gaza, Esquire, hereby certify that on June 12, 2019, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to all registered participants.

I further certify that on June 12, 2019**,** I caused the foregoing document to be served by e-mail on the following counsel of record:

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